HFI-35 - no purging needed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2316n

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 19 1999

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Steven Daffer
President
Sybaritic, Incorporated
9220 James Avenue South
Minneapolis, Minnesota 55431

Re: GX-99 Massage Therapy System

Dear Mr. Daffer:

The Food and Drug Administration (FDA) has reviewed promotional materials for the GX-99 Massage Therapy System (GX-99)(a.k.a. G-5 and/or GX-99 Vibratory Endermatherapie™ Cellulite Treatment). The GX-99 is manufactured by Sybaritic, Incorporated (Sybaritic) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The promotional materials we reviewed include the following: (1) The Alpha Spa™ Treatment Manual (#206036-REV 10/98); (2) a flyer titled, Introducing GX-99 Vibratory Endermatherapie™ System (#202013 REV 3/98); (3) a brochure titled, GX-99 Body Treatments (#206037 REV 1/98); and, (4) several pages from your web site at the internet address: http://www.sybaritic.com. The brochures and flyers were obtained from the Sybaritic exhibit booth at the November 9-11, 1998, ISPA convention which was held in Colorado Springs, Colorado.

On March 17, 1998, you were advised by this office that before Sybaritic may make claims for the GX-99 related to a reduction in cellulite, you must either (1) demonstrate that the claim "temporarily reduces the appearance of cellulite" falls within the exempted status of the device, and results from the indications that are recognized by the Agency i.e., temporary increase in local blood circulation, relaxation of muscles locally, relief of minor muscles aches and pains; (2) file a new 510(k) premarket notification for the claim, or (3) petition the agency to include the claim as part of the exemption for therapeutic massagers. Your response from Mr. Ronald E. Berglund, Sybaritic General Counsel dated April 7, 1998, indicated that no further claims for

submitting additional data to support claims of slimming and drainage of lymph resulting from the increase in local blood circulation.

Despite these commitments, the above promotional materials, including those from your web site, continue to make claims for cellulite reduction, slimming, and drainage of lymph. Additionally, these materials also contain the following claims for the GX-99: Deep tissue contouring; treatment for sinus and nasal congestion; headaches, ayurvedic treatments, improving nutrition and lessening inflammation to joints; reduction of swelling following injury; promoting detoxification; help mobilize and eliminate long-established fat deposits; enhances the removal of waste products; increases secretion of natural oils; reduces risk of bacterial infection; helps delay new wrinkles and diminishes the appearance of skin imperfections and scar tissue; speeds recovery from injuries; and, relieves fatigue and hastens the elimination of lactic acid.

All of the above claims go beyond those recognized by the agency for therapeutic massagers and remove your device from its exempted status. Continued promotion of the GX-99 for these claims causes the device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

Additionally, the GX-99 is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modifications in the intended use(s) of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your GX-99 device. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Minneapolis District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Minneapolis District Office (HFR-MW300), 240 Hennepin Avenue, Minneapolis, Minnesota 55401-1912.

Sincerely yours,

Byron Tart for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health